CLAIMS

1. Anti-human tenascin monocloncal antibody, preferably murine, whose light and heavy chain variable region sequences are SEQ ID NO: 1 and SEQ ID NO: 2, respectively, its proteolytic fragments capable of binding to an antigenic epitope within the $A_{(1-4)}$-D region of human tenascin, its recombinant derivatives, its conjugates and similar functional analogues capable of binding to an antigenic epitope within the $A_{(1-4)}$-D region of human tenascin.

2. Fragments of the antibody according to claim 1, optionally containing additional markers and diagnostic agents.

3. Recombinant derivative of the antibody according to claim 1, in which the murine constant region is replaced by its human counterpart.

4. Recombinant derivative of the antibody according to claim 1, in which the murine constant region is replaced by a biologically active component.

5. Recombinant derivative of the antibody according to claim 1, in which the murine constant region is replaced by a pharmacologically active component.

6. Recombinant derivative of the antibody according to claim 1, in which the murine constant region is replaced by a member of the avidin family.

7. Derivatives of the antibody according to claim 1 conjugated with biologically active substances.

8. Biotinylated antibody according to claim 1 or biotinylated fragments according to claim 2, or biotinylated derivatives according to claims 4-7.

9. DNA encoding the antibody according to claim 1 or fragments according to claim 2.

10. A vector containing the DNA according to claim 9.

11. Host cell containing the vector according to claim 10.

12. Protein coded for by the nucleotide sequences SEQ ID NO: 1 and SEQ ID NO: 2 or its fragments.

13. DNA encoding the protein or its fragments according to claim 12.

14. Specific CDRs (Complementary Determining Regions) of the antibody according to claim 1 and proteins containing said CDRs.

15. Hybridoma producing the antibody according to claim 1, deposited at the Centro di Biotecnologie Avanzate, Largo Rossana Benzi 10, Genoa – Italy on 12 November 2003 in accordance with the provisions of the Budapest Treaty, under deposit number PD03003.

16. Process for the preparation of the antibody according to claim 1 comprising

a) immunisation of an animal with the $A_{(1-4)}$-D fragment of human tenascin;

b) fusion of somatic spleen cells of said animal with myeloma cells not producing immunoglobulins;

c) selection of the monoclonal antibody.

17. Use of the antibody or its proteolytic fragments or its recombinant derivatives or its conjugates or analogues according to claim 1, optionally biotinylated, or of its fragments according to claim

2, optionally biotinylated, or of its biotinylated derivatives according to claims 4-7 for the preparation of a pharmaceutical product useful for the treatment or diagnosis of a disease characterised by expression of tenascin.

18. Use according to claim 17, in which said disease is a tumour.

19. Use according to claim 18, in which said tumour is selected from the group consisting of glioma, cancer of the breast, carcinoma of the lung, fibrosarcoma and squamous-cell carcinoma.

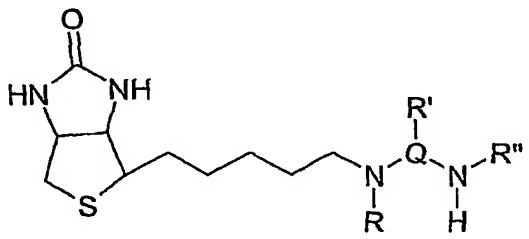
20. Use of the antibody or its proteolytic fragments or its recombinant derivatives or its conjugates or analogues according to claim 1, optionally biotinylated, or of its fragments according to claim 2, optionally biotinylated, or of its biotinylated derivatives according to claims 4-7 for the preparation of a pharmaceutical product useful for the two-stage perioperative therapy of solid tumours.

21. Pharmaceutical or diagnostic compositions containing an antibody or its proteolytic fragments or its recombinant derivatives or its conjugates or analogues according to claim 1, optionally biotinylated, or its fragments according to claim 2, optionally biotinylated, or its biotinylated derivatives according to claims 4-7 in mixtures with at least one pharmaceutically acceptable vehicle and/or excipient.

22. Kit for systemic radioimmunotherapy, particularly three-step pre-targeting radioimmunotherapy, consisting of 5 vials: vial 1 containing an antibody or its proteolytic fragments or its recombinant derivatives or its conjugates or analogues according to claim 1, optionally biotinylated, or fragments according to claim 2, optionally biotinylated, or biotinylated derivatives according to claims 4-7; vial 2 containing avidin; vial 3 containing streptavidin; vial 4 containing biotinylated human albumin; and vial 5 containing biotin DOTA.

23. Kit for locoregional radioimmunotherapy consisting of 3 vials; vial 1 containing an antibody or its proteolytic fragments or its recombinant derivatives or its conjugates or analogues according to claim 1, optionally biotinylated, or its fragments according to claim 2, optionally biotinylated, or biotinylated derivatives according to claims 4-7; vial 2 containing avidin; and vial 3 containing biotin DOTA.

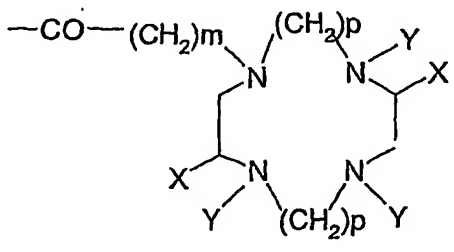
24. Kit according to claim 22 or 23, in which, said biotin DOTA in vial 5 or vial 3, respectively, is the formula (I) compound



(I)

in which Q is a $-(CH_2)n-$ group, where n is a whole number from 4 to 12, in which case R' is not present, or Q is selected from the group consisting of $-(CH_2)_a-CH(R')_b-(CH_2)_b-$, where a and b are independently whole numbers from 0 to n, R' is as defined here below, or Q is cyclohexyl, phenyl, in which case R' is a substituent on the cyclohexyl or phenyl ring;

R is hydrogen or -Λ where -Λ is a formula (II) macrocycle,



(II)

where the various Y's, which may be the same or different, are selected from the group consisting of hydrogen, straight or branched C_1-C_4 alkyl, -$(CH_2)_m$-COOH, where m is a whole number from 1 to 3, X is hydrogen, or the group -CH_2-U, where U is selected from the group consisting of methyl, ethyl, and p-aminophenyl, or X is the group -$(CHW)_o$-Z, where o is a whole number from 1 to 5, W is hydrogen, methyl or ethyl, Z is a 5- or 6-member heterocyclic group containing one or more heteroatoms selected from O, N-R_1, where R_1 is hydrogen or straight or branched C_1-C_4 alkyl, and S; or Z is selected from the group consisting of –NH_2, -NH-C(=NH)-NH_2, or -S-R_2, where R_2 is straight or branched C_1-C_4 alkyl;
p is the number 2 or 3;
R' is selected from the group consisting of hydrogen, straight or branched C_1-C_4 alkyl, -$(CH_2)_q$-T, in which T is selected from the group consisting of -S-CH_3, -OH, -COOH, and q is the number 1 or 2;
R'' has the same meanings as R', upon the following conditions: if R is -Λ, R'' is hydrogen; if R is hydrogen, R'' is -Λ, or R and R'' are, respectively, -$(CH_2)_r$-Λ (for R), where r is a whole number from 4 to 12, and -Λ (for R'), Q being a -$(CH_2)_n$- group, where n is a whole number from 4 to 12.

25. Kit according to any one of claims 22-24, in which vial 3 contains an avidin dimer in which two avidin molecules are bound via the -NH_2 groups by means of suberate.

26. Kit according to any one of claims 22-24, in which said vial 3 contains an avidin dimer in which two avidin molecules are bound via the –COOH groups by means of polyethylene glycol with a molecular weight of 3,400.

27. Kit according to claim 22 or 23, in which the antibody or its proteolytic fragments or its recombinant derivatives or its conjugates or analogues according to claim 1, optionally biotinylated, or its fragments according to claim 2, optionally biotinylated, or its

biotinylated derivatives according to claims 4-7, are combined with other anti-tenascin antibodies, preferably targeting the EGF-like region of the protein.

28. Kit according to claim 22 or 23, in which the antibody or its proteolytic fragments, or its recombinant derivatives or its conjugates or analogues according to claim 1, optionally biotinylated, or its fragments according to claim 2, optionally biotinylated, or its biotinlyted derivatives according to claims 4-7, are combined with other tumour-specific antibodies.

29. Use of the antibody or its proteolytic fragments or its recombinant derivatives or its conjugates or analogues according to claim 1, optionally biotinylated, or its fragments according to claim 2, optionally biotinylated, or its biotinylated derivatives according to claims 4-7, in the preparation of compositions useful in the tumour immunolocalisation procedure.

30. Container, preferably in the form of a vial, suitable for injection, containing an antibody or its proteolytic fragments or its recombinant derivatives or its conjugates or analogues according to claim 1, optionally biotinylated, and/or radiolabelled or its fragments according to claim 2, optionally biotinylated, or its biotinylated derivatives according to claims 4-7.

31. Tumour imaging method including the administration of an antibody or its proteolytic fragments or its recombinant derivatives or its conjugates or analogues according to claim 1, optionally biotinylated, or its fragments according to claim 2, optionally biotinylated, or its biotinylated derivatives according to claims 4-7 to a person suffering from or suspected of suffering from a tumour, and the detection of said tumour.

32. Method according to claim 31, in which the antibody or its proteolytic fragments or recombinant derivatives or conjugates or analogues are radiolabelled.

33. Combination containing the antibody or its proteolytic fragments or recombinant derivatives or conjugates or analogues according to claim 1, or fragments according to claim 2, or derivatives according to claims 4-7 and a second tenascin-specific antibody.

34. Use of the combination according to claim 33 in a sandwich-type *in-vitro* ELISA assay, in conditions in which said second antibody binds to a second antigenic epitope, for the purposes of determining circulating tenascin levels, particularly levels of the isoforms containing the $A_{(1-4)}$-D region.